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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,295	02/12/2004	Delbert E. Day	UMO 1553.3	5755
321 7590 07/15/2009 SENNIGER POWERS LLP 100 NORTH BROADWAY 17TH FLOOR ST LOUIS, MO 63102				
EXAMINER HELM, CARALYNNE E				
ART UNIT		PAPER NUMBER		
1615				
NOTIFICATION DATE		DELIVERY MODE		
07/15/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

### Office Action Summary

**Application No.**

10/777,295

**Applicant(s)**

DAY ET AL.

**Examiner**

CARALYNNE HELM

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 April 2009.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 and 55-91 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-7 and 55-91 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

Note to Applicant: References to paragraphs in non-patent literature refer to full paragraphs (e.g. 'page 1 column 1 paragraph 1' refers to the first full paragraph on page 1 in column 1 of the reference)

## MAINTAINED REJECTIONS

### Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 55-65 and 68 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6-7 of U.S. Patent No. 6,709,744. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a particle with hydroxyapatite that is in shaped form. Instant claims 55-65 are recited as product-by-process claims. "[E]ven

though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) MPEP 2113. Although instant claim 55 requires that the final product take on the shape of the molded (shaped) water-soluble glass, no particular shape is required. Thus no structure is added by the limitations regarding the glass. Therefore claims 55-65 and 68 are obvious over claims 1 and 6-7 of U.S. Patent No. 6,709,744.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-4, 55-65, and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (WO96/29144).

Instant claims 1, 3-4, 55-65, and 67 are recited as product-by-process claims. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a

product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) MPEP 2113. Although both instant claim 1 and 55 require that the final product take on the shape of the water-soluble glass, no particular shape is required. Thus no structure is added by the limitations regarding the glass bodies.

Brown teaches an agglomerate/shaped body of calcium phosphate particles (see example 1; instant claim 1). The particles used to make the agglomerates are at minimum 1  $\mu\text{m}$  in diameter (see page 24 lines 20-31; instant claims 3-4). Thus the smallest agglomerate would contain at least two particles and measure at least 2  $\mu\text{m}$ . After the calcium phosphate agglomerates are made, Brown teaches their immersion in aqueous liquid and conversion of these agglomerates into hydroxyapatite (see page 25 lines 19-25; instant claims 55-65 and 67). Therefore claims 1, 3-4, 55-65, and 67 are unpatentable over Brown.

### **NEW REJECTIONS**

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

All of the instant claims are recited as product-by-process claims. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even

though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) MPEP 2113. Although both instant claim 1 and 55 require that the final product take on substantially the same shape as the water-soluble glass, there is no stipulation on how similar bodies that are "substantially the same" shape must be. In addition, in the instances where the glass bodies have no particular claimed shape, the calcium phosphate bodies can have any shape. Further, limitations drawn to the particular connectivity of the glass bodies or they way in which they are formed add no structure to the final product since these glass bodies are not present in the final product. Thus the prior art need only provide a product that is a calcium phosphate agglomerate or hydroxyapatite structure capable of being made by the glass bodies with the recited shapes.

Claims 1-7, 67, 87-88, and 90-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al (previously cited).

Day et al. teach porous, hollow shell particles that formed on the surface of solid borate based glass templates that dissolve away (see column 3 lines 56-64 and column 5 line 66-column 6 line 2; instant claims 5-7). The particles are taught to be irregularly shaped or an assemblage of microspheres (agglomerate) (note: a sphere is an ellipsoid where the major axis and minor axis are of equal length) (see column 6 lines 5-8; instant claims 1, 4, 87-88, and 90-91). The particles are taught to range in size from 5  $\mu\text{m}$  to 1000  $\mu\text{m}$  (see column 6 lines 9-10; instant claim 3). In addition, Day et al. teach calcium and phosphorous (calcium phosphate) being in the particle products and the

suitability of these structures for in vivo bone growth and as bone repair agents (see column 6 lines 29-32 and column 7 lines 35-38; instant claims 1, 4, and 67). Since the particles of Day et al. are shells that form on the outside of the glass template structures, the number of glass structures will determine the number of calcium phosphate bodies in the final product. The particular end use and final size desired for the particles can be readily determined by one of ordinary skill in the art, thus the number of calcium phosphate bodies in each particle would have been matter of routine experimentation at the time of the invention (see instant claim 2). Therefore claims 1-7, 67, and 87-88 are obvious over Day et al.

Claims 55-65 and 68-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al. as applied to claims 1-7, 67, 87-88, and 90-91 above, and further in view of Hayakawa et al.(previously cited).

The process of making the calcium phosphate particles taught by Day et al. requires that the borate based glass (exemplified as 11.25%  $\text{Li}_2\text{O}$ , 78.75%  $\text{B}_2\text{O}_3$ , and 10%  $\text{CaO}$ ) be soaked in a phosphate containing solution, such as a saline or body fluid (see column 8 lines 31-45; instant claims 69-74). The reaction of Ca from the glass with hydroxide and/or phosphate ions from the solution forms the particle structure (see column 4 lines 3-19). The structure forms on the glass surface, taking on its shape and gradually dissolving the glass away as the reaction product forms (see column 4 lines 3-19). Day et al. exemplify the immersion of the glass into a phosphate buffered saline solution where there is a 0.3M inorganic ion concentration and the solution temperature



is 37°C (see column 7 lines 35-38 and column 8 lines 1-8; instant claims 68, 77-78, and 81-82). The reaction rate depends upon the metal oxide incorporated into the glass which coupled with the size of the glass being reacted, determines the time for immersion. Since the particles can be from 5 to 1000  $\mu\text{m}$  and the reaction rate for CaO is 7  $\mu\text{m}/\text{h}$ , the reaction/immersion time ranges from slightly less than an hour to 6 days (see column 8 lines 31-45; instant claims 75-76). Day et al. does not explicitly teach that the form of calcium phosphate in the formed particles is hydroxyapatite or that the pH of the immersion solution used in the process.

Hayakawa et al. teach the formation of apatite on the surface of calcium containing sodium silicate glass upon soaking for several hours to days in simulated body fluid that contains phosphate ions (see section II paragraph 1 and table III). It was known that soaking borate based glass in saline or body fluid forms surface calcium phosphate (the base constituents of hydroxyapatite) and both hydroxide and phosphate ions react with the calcium in the glass based on the teachings of Day et al. This together with the knowledge that soaking silicate based glass in body fluid forms surface apatite from Hayakawa et al. would have made it obvious to one of ordinary skill in the art at the time of the invention to form hydroxyapatite in the invention of Day et al. (given optimization of the appropriate molar ratios and incubation time). Since Day et al. teach the utility of their particles in bone applications and hydroxyapatite is a very well known form of calcium phosphate used in such applications, one of ordinary skill in the art would have found it obvious to optimize the immersion time and ion proportions in the immersion solution to obtain this form of calcium phosphate (see instant claims 55-

65). Further, since physiological fluids are known for the process taught by Day et al. (e.g. body fluid), it would have been obvious to set the pH of the immersion solution to that of body fluid, namely neutral pH (also interpreted to correspond "about 9"; see instant claims 79-80 and 83). Therefore claims 55-65 and 68-83 are obvious over Day et al. in view of Hayakawa et al.

Claims 1, 55, 66, 84-86, and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al. in view of Hayakawa et al. as applied to claims 55-65 and 68-82 above, and further in view of Jin et al. (previously cited).

Day et al. in view of Hayakawa et al. make obvious the hydroxyapatite particle of instant claim 55 but do not explicitly teach it to be shaped as a rod, bar, cube, or ellipsoid.

Jin et al. teach that hydroxyapatite particles were known to be shaped in rod form for bone applications (see page 491 column 1 paragraph 1 and page 492 column 2 paragraph 1). Since Day et al. specifically teach their particles for use in in vivo bone applications, it would have been obvious to one of ordinary skill in the art at the time of the invention to shape the particles or agglomerates of Day et al. in view of Hayakawa et al. in rods. As Day et al. also teach that the final calcium phosphate product takes on the shape of the template used, it would have been obvious to one of ordinary skill in the art that a collection of rod, fiber, cube or bar shaped glass templates would be capable of forming such a final rod shape. Since this glass is not present in the final product, only contributes some semblance of its shape to this product, and a final rod

shape was known at the time of the invention, the structure conferred by the rod, fiber, cube or bar shaped glass particles of instant claims 84-86, and 89 is also present in the invention of Day et al. in view of Hayakawa et al. and Jin et al. Therefore claims 55, 66, 84-86, and 89 are obvious over Day et al. in view of Hayakawa et al. and Jin et al.

### ***Response to Arguments***

Applicant's arguments submitted April 23, 2009 have been considered but are not persuasive.

#### ***Regarding rejection under 35 USC 102(b):***

Applicant argues that the method of production taught by Brown is different than that of the instant claims and for this reason, Brown does not teach the claimed product. Applicant has claimed a product. Although this product is framed as a product-by-process where the desired process steps are recited in the claim, the invention claimed is still a product that is defined by explicitly recited components and the structure, if any, conferred by the process. The final product at the end of the process steps of both the instant claims and Brown is a calcium phosphate agglomerate. Although it is true that the path taken by the instant claims and Brown to reach this endpoint is not the same, there is not evidence then the end products are at all different. Applicant has not provided any evidence that demonstrates how the recited method steps in the instant claims add structure to the end product that is not also achieved in the end product of Brown. Applicant even concedes that "Brown makes an agglomeration of calcium

phosphate bodies.” (see remarks page 9 paragraph 1). This agglomeration of calcium phosphate bodies is the same as the calcium phosphate agglomerate product as instantly claimed. Although applicant also requires that the agglomerate have substantially the same shape as the agglomeration of the plurality of water soluble glass bodies, applicant has not established how close to the glass bodies’ shape the final agglomerate must be in order to be ‘substantially the same’. At most, the structure conferred by this requirement is that the final product have a shape that is to some degree similar to a starting template material. Brown teaches that his agglomerates are made from a template particle agglomerate that is converted into the final calcium phosphate agglomerate. Thus whatever shape results can reasonably be interpreted as substantially the same as the starting particle agglomerate. However in point of fact, no particular shape is actually required for the product of claim 1 or 55 since applicant recites no particular shape for the glass material used in the process of making the calcium phosphate agglomerates. Since applicant teaches that the glass bodies dissolve away, their composition and presence in the process is ultimately immaterial to the claimed product.

*Regarding rejections under 35 USC 103(a):*

Applicant argues that Day et al. teach calcium phosphate spheres or irregularly shaped particles which are different than the agglomerate of calcium phosphate bodies instantly claimed. While it is true that Day et al. teach their products to be spherical as well as irregularly shaped calcium phosphate particles, Day et al. also teach that these

calcium phosphate structures can take the form of an assemblage of microspheres which is reasonably interpreted as an agglomerate (see column 6 lines 5-9). Chambers 21<sup>st</sup> Century Dictionary defines an assemblage as a collection of people or things and an agglomerate as an untidy mass or collection of things. Thus the interpretation of 'assemblage' and 'agglomerate' as synonymous terms is certainly reasonable.

Applicant also argues that Day et al. does not teach an agglomerate of glass bodies. As applicant has noted, glass bodies are not present in the final product being claimed, therefore it is not necessary that Day et al. teach this element in their product in order to render obvious the instant invention. However, Day et al. teach that the products of their invention are formed by the immersion of glass particles in an aqueous solution such that an insoluble material forms that is essentially the same shape as the particles (see column 4 lines 3-10). Since Day et al. also teach an assemblage of microspheres as a final product shape it would follow that the starting material was also an assemblage of glass particles. So although not necessary to render the product of the instant claims obvious, Day et al. implicitly teaches a assemblage/agglomerate of glass particles.

Applicant goes on to argue that Day et al. do not teach an agglomerate with at least about 10 calcium phosphate bodies. Day et al. clearly teach an assemblage/agglomerate of calcium phosphate bodies which at minimum requires 2 calcium phosphate bodies. Since applicant has not provided a way to determine how many particles corresponds to "about 10", a broad, yet reasonable interpretation of this number would include 2. Furthermore, one of ordinary skill in the art would be more

than capable and find it obvious to select the number of particles in the assemblage/agglomerate based upon the requires of the end use requirements of the material (e.g. drug delivery bone repair, etc.). Therefore optimization during the course of routine experimentation would certainly meet this claim limitation.

Applicant argues that Day et al, does not teach transforming molded soluble glass particles and thus cannot produce particles that have substantially the same shape as these molded articles. "Molding" in and of itself does not confer any particular structure to the final product that is unique to the act of molding. As applicant has noted, glass bodies are not present in the final product being claimed, therefore it is not necessary that Day et al. teach this element in their product in order to render obvious the instant invention. However, Day et al. teach that the products of their invention are formed by the immersion of glass particles in an aqueous solution such that an insoluble material forms that is essentially the same shape as the particles (see column 4 lines 3-10). Regardless of how the glass particles are formed (molding, sintering grinding, blowing, crushing, etching, etc.), the product taught by Day et al, will have essentially (substantially) the same shape as these particles. Since this is the case, one of ordinary skill would be well equipped to shape the glass starting material of Day et al. into any shape via any methodology within their technical grasp. Furthermore, as discussed above, the instant invention is drawn to a product and the recitation of 'molded' water-soluble glass does not confer any structural limitations to this product.

Applicant argues that because Hayakawa et al. teach the deposition of hydroxyapatite on glass particles that are crushed one of ordinary skill in the art would

not have been motivated to start with molded glass. Day et al. teach that the products of their invention are formed by the immersion of glass particles in an aqueous solution such that an insoluble material forms that is essentially the same shape as the particles (see column 4 lines 3-10). Regardless of how the glass particles are formed (molding, sintering grinding, blowing, crushing, etching, etc.), the product taught by Day et al, will have essentially (substantially) the same shape as these particles. Since this is the case, one of ordinary skill would be well equipped to shape the glass starting material of Day et al. into any shape via any methodology within their technical grasp. Furthermore, as discussed above, the instant invention is drawn to a product and the recitation of 'molded' water-soluble glass does not confer any structural limitations to this product.

Applicant argues that based on Hayakawa et al.'s teachings of silicate glass formers, one of ordinary skill in the art would not have been led to believe that a borate based glass would have the same reactivity. Contrary to this assertion by applicant, it was known at the time of the invention that, like the silicate glass of Hayakawa et al., borate glasses also form hydroxyapatite on their surface when in aqueous simulated body fluid (see Wojcik Hydroxyapatite formation on silicate and borate glass 1999 page 4 paragraph 1 and page 12 paragraph 2). Applicant continues with the argument stating that one of ordinary skill would not have been motivated to exchange the borate of claim 56 for the silicate of Hayakawa et al. The rejection did not suggest this exchange but instead pointed to Hayakawa et al. to identify the likely forms of calcium phosphate that would form in the invention of Day et al. given the application of bodily (or simulated bodily) fluid in their preparation process.

Finally, applicant argues that Jin et al. does not teach hydroxyapatite particles prepared by the method recited in the instant product claims and therefore does not render the claimed invention obvious. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Jin et al. teaches that rod shaped hydroxyapatite particles were known at the time of the invention particularly for applications in bone. Since Day et al. explicitly envision their particles for such an applicant, it would have been obvious to one of ordinary skill to shape their particles in this fashion (see column 6 lines 29-32). This teaching combined with those of Day et al. and Hayakawa et al. renders obvious the claimed invention.

Applicant has provided no evidence to demonstrate that the process steps touted as distinguishing the instant invention from those of the prior art in any way provides a structural feature to the final product that is not also present in the prior art products. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). ...The structure implied by the process steps should be considered when assessing the patentability of



product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)" (see MPEP 2113). Therefore when no structure is implied, the product-by-process recitation does not add any limitations that affect patentability.

*Regarding rejection under non-statutory double patenting:*

Applicant argues that because the instant claims exclude glass containing 20-35 wt% CaO, 20-35 wt % Na<sub>2</sub>O, 0-10 wt% P<sub>2</sub>O<sub>5</sub> and 30-50 wt% B<sub>2</sub>O<sub>3</sub> from the process of preparing the claimed product that the claims of US Patent No. 6,709,744, which require this component cannot make obvious the claimed invention. Although it is true that applicant excludes this variety of material from the method of making the claimed product applicant, it is not excluded from the final product. In fact, a glass is not a claimed element of the actual final product. Therefore the nature of a material that is only present during the preparation process is not material to the patentability of the product. Thus claims 55-65 and 68 are unpatentable of the recitation of a hydroxyapatite particle in claims 1 and 6-7 of US Patent No. 6,709,744.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The rejections and/or objections detailed above are either reiterated

or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **CARALYNNE HELM** whose telephone number is (571)270-3506. The examiner can normally be reached on **Monday through Thursday 8-5 (EDT)**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/  
Examiner, Art Unit 1615

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615